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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Criere	017751-030	8894

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,262

Applicant(s)

CRIERE ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

The use of the trademark Polysorbate and Montane has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

Claims 3-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation between 2.4 and 18 cP, and the claim also recites between 2.4 and 3.6 cP, which is the narrower statement of the range/limitation.

In the present instance, claim 4 recites the broad recitation greater than or equal to 70%, and the claim also recites greater than or equal to 75%, which is the narrower statement of the range/limitation.

In the present instance, claim 6 recites the broad recitation surfactant between 1 and 10%, and the claim also recites surfactant between 3 and 5%, which is the narrower statement of the range/limitation.

In the present instance, claim 8 recites the broad recitation between 2 and 15%, and the claim also recites between 5 and 12%, which is the narrower statement of the range/limitation.

In the present instance, claim 10 recites the broad recitation particles is less than 15 microns, and the claim also recites less than 8 microns, which is the narrower statement of the range/limitation.

Regarding claim 9, the phrase "for instance" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further it is noted that claim 5 refers to surfactants as trademark names, which is indefinite because of a trademark name does not necessarily reflect the compound and may be a

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composition. Accordingly, it is suggested that the trademark name is replaced with the actual compounds or compounds intended to be claimed.

Claims-minor informalities

Examiner notes that the dependent claims 5 through 12 recite the expression "claimed in one of the preceding claims". Examiner suggests applicants to amend the above claims to read as "claimed in any one of the preceding claims" in order to be appropriately dependent from preceding claims. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,628 ('628) in view of U.S. Patent No. 6,074,670 ('670) or over '670 itself.

'628 teach pharmaceutical composition comprising effective amounts of fenofibrate and excipients and suspension stabilizers. Among the suspension stabilizers, '628 teach cellulose derivatives including hydroxypropylmethyl cellulose (HPMC) (col. 2, lines 44-53), and the excipients of '628 include one or more of polyglycolized glycerides such as Gelucire or

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poloxamer (col. 3, lines 1-35 and col. 4, lines 26-35), both of which read on the instant surfactant. '628 teach fenofibrate in the amount of 5% to 95%, preferably 45% to 55% (col. 3).

'670 teach immediate release fenofibrate composition comprising micronized fenofibrate, having a particle size of less than 20 microns or even less than 10 microns (col. 3, lines 65-67), excipients selected from sugars, starches or celluloses such as HPMC (col. 4) and surfactants including sodium lauryl sulfate poloxamer etc (col. 4). '670 teach a ratio of fenofibrate to hydrophilic polymer between 1/10 and 4/1 (col. 5) and teach up to 40% fenofibrate by weight of the composition. '670 further suggests the same process of preparing the composition i.e., spraying a suspension of micronized fenofibrate together with a hydrophilic polymer such as cellulose and a surfactant (col. 5, lines 30-35)

'628 do not teach micronized fenofibrate, claimed percentage of fenofibrate or the process of preparing fenofibrate as claimed. '628 also fail to teach the claimed viscosity of HPMC. '670 fail to teach fenofibrate above 60% and the claimed ratios and viscosities. However, the teaching of '670 is analogous to the instant invention in that '670 is also directed to increasing the bioavailability of fenofibrate, despite the art known formulations containing micronized fenofibrate, cellulose derivatives and surfactant. '670 suggest spraying a suspension of fenofibrate (micronized), polymer and a surfactant on an inert core (reads on instant inert granules) improves the bioavailability. Examiner notes that instant specification also is directed to increased bioavailability and is achieved by the same method as that of '670. While '670 teaches fenofibrate up to 40% and not at least 60% as claimed, '670 is in the same field of endeavor and solving the same problem of increased bioavailability of fenofibrate. Accordingly,

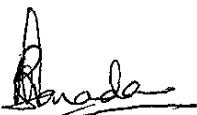
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absent evidence to the contrary optimizing the amount of fenofibrate in the composition of '670 with expectation to obtain the desired dissolution profile of fenofibrate would have been within the scope of a skilled artisan. Alternatively, it would have been obvious for a skilled artisan at the time of the instant invention to prepare a composition containing micronized fenofibrate employing the process of preparing the fenofibrate composition (as taught by '670) in the teachings of '628 because, '670 teaches that the process enables a complete bioavailability of fenofibrate in a very short period of time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438 or (571)-272-0591 after February 3, 2003. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927 or (571)-272-0602 after February 3, 2004. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
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January 9, 2004